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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,377	09/14/2006	Alastair David Griffiths Lawson	13001012PCTUS	1120

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EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,377	LAWSON ET AL.	
	Examiner	Art Unit	
	David A. Saunders	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-19* is/are pending in the application.

4a) Of the above claim(s) *8,9 and 11-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,7 and 19* is/are rejected.

7)☒ Claim(s) *2 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/5/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-19 are pending.

RESPONSE TO ELECTION/RESTRICTION

Applicant's election without traverse of Group I (claims 1-7 and 19, as set forth in the restriction mailed on 1/2/09) in the reply filed on 2/2/09 is acknowledged.

REJECTION(S) UNDER 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Irsch et al (5,786,161, cited on PTO-1449).

Irsch et al teach a method of isolating B-cells which produce an antibody which recognizes an allergen/antigen; see disclosure of B-cells at col. 4, lines 9-11. A population of B-cells is contacted with an allergen coupled to a hapten, and these are incubated so that allergen can bind to cell surface bound antibody/immunoglobulin (Ig); see col. 6, lines 7-17. The thus incubated cells are then contacted with avidin coated magnetic particles, to which a biotinylated anti-hapten antibody has been complexed. See col. 6, lines 19-23. This second binding step forms a sandwich complex of:

B-cells --- hapten-antigen --- biotinylated-antibodies-avidin-beads.

From these teachings instant claim 1 is anticipated, particularly for the order of contacting set forth in dependent claim 3.

Clearly, dependent claim 6 is anticipated, since Irsch et al teach magnetic separation; see col. 6, lines 22-23 and col. 6, line 49-col. 7, line 34.

The above stated rejection is proper, since nothing in the claim language rules out the use of an antigen coupled to another moiety, such as a hapten.

REJECTION(S) UNDER 35 USC 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irsch et al alone or in view of Steenbakkers (EP 0,448,470, A1, Cited on PTO-892).

Irsch et al have been cited above for showing the steps of claim 1, in which B-cells that produce an antibody that recognizes an antigen are isolated. Irsch et al give hints that one might want to immortalize the selected cells, in order to produce antibodies (e.g. col. 4, lines 9-22; col. 8, lines 12-22). Irsch et al do not point out all of the steps involved in such production of antibodies from the immortalized cells. However, Steenbakkers teaches one how to isolate individual B-cell or a population of B-cells that produce an antibody that recognizes an

antigen. Among the methods for isolating such antigen-specific B-cells are those involving the use of magnetic/paramagnetic beads (p 4, lines 10-14). Thus one practicing the methods of Steenbakkers would have found it obvious to have connected the teachings of Steenbakkers with the cell isolation methods of Irsch et al. Steenbakkers further teaches that such isolated B-cells that produce an antibody that recognizes an antigen can be cultured (i.e subjected to clonal expansion, immortalized, further cultured, and used to produce antibodies (e.g. p 3, lines 35-40). Note teachings of screening cultures for production of a specific antibody (e.g. Tables at pp 9-14). Thus the further steps of culturing, screening and isolating an antibody from the B-cells selected by the method of Irsch et al would have been obvious.

Claims 1, 3-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irsch et al in view of Brown et al (WO 04/051268, cited in IDS of 6/5/06).

Reliance upon Brown et al (WO 04/051268) is proper under 102(e), since the instant record has not established that Brown et al (WO 2004/051268) and the instant inventors were subject to common assignment at the time both of the inventions were made. Furthermore, citation of Brown et al (WO 2004/051268) is proper because applicant cannot claim benefit of the earliest GB priority date of 20 Aug 2003 (priority document 0319587.2 only shows the "homogenous" assay of Brown et al (WO 04/051268) and does not show the instant-non-homogenous/ heterogenous assay). Therefore the International Filing Date of 01 Dec 2003 for WO 2004/051268 renders this reference effective under 102(e).

Irsch et al have been cited supra for showing a method in which the "antigen of interest" carries a hapten, and in which the particle bears an anti-hapten antibody. Brown et al show a method in which one, likewise, forms a complex in which antigen recognized by an antibody becomes indirectly bound to a particle; this antigen bearing particle is employed in a method of binding antigen-specific B-cells. In the case of Brown et al, the complex is formed

between antigen, not coupled to anything, and a particle-immobilized polyclonal antibody that recognizes the antigen. See p 8, lines 11-29. One of ordinary skill would have recognized that the method of Irsch et al, in which one forms a complex consisting of antigen-hapten and anti-hapten, and the method of Brown et al, in which one forms a complex consisting of antigen and anti-antigen antibody are equivalent ways of indirectly providing a particle bearing an antigen which can be recognized by antigen specific B-cells. Even though the methods of Irsch et al and Brown et al may differ in the way they use the particles (i.e. the former teach a "heterogeneous" method involving separation step(s) and the latter teach a "homogeneous" method involving no separation step), the particles in each case are of the same nature. Thus, whether then antigen is indirectly bound to a particle via hapten-anti-hapten binding (as in Irsch et al) or via antigen-anti-antigen binding (as in Brown et al) makes no difference as to whether the particles could be used in one of the taught methods or the other. Therefore it would have been obvious to use particles with antigen indirectly coupled via antigen-anti-antigen binding (as in Brown et al) in the cell B-cell isolation method of Irsch et al. Thus instant claim 1, would have been obvious.

Instant claim 3 would have been obvious, if one were to consider following the order of addition of components as taught by Irsch et al.

Instant claim 4 would have been obvious, if one were to consider following the order of addition of components as taught by Brown et al (e.g. p 8, lines 23-19).

Regarding claim 6, Brown et al teach that the particles can be magnetic (p 8, line 9).

Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irsch et al in view of Brown et al and further in view of Steenbakkers et al.

Irsch et al and Brown et al have been cited above for showing that the steps of claim 1, in which B-cells that produce an antibody that recognizes an

antigen are isolated, would have been obvious. Irsch et al give hints that one might want to immortalize the selected cells, in order to produce antibodies (e.g. col. 4, lines 9-22; col. 8, lines 12-22). Irsch et al do not point out all of the steps involved in such production of antibodies from the immortalized cells. However, Steenbakkers teaches that one can isolate individual B-cell or a population of B-cells that produce an antibody that recognizes an antigen and then, further, that one can culture (clonally expand), immortalize, further culture, and use the cells to produce antibodies (p 3, lines 35-40). The rational for reliance upon the further teachings of Steenbakkers follows that set forth supra, in the rejection over Irsch et al in view of Steenbakkers.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays. The examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see http://pair-direct.uspto.gov. If you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 5/6/09 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644